Remarks

I. Support For The Amendment And Reasons For Entry Of The Amendment

Applicants propose to amend Claim 7. Support for the proposed amendment of Claim 7 is found in the application as filed in original Claim 15.

Applicants propose to amend Claim 9 to correct the pendency, such that claim 9 will depend from Claim 7.

No new matter will be added by the proposed amendment.

Entry of the proposed amendment will not raise new issues that would require further consideration and/or search.

Alternatively, entry of the proposed amendment will place the application in better form for allowance or appeal, should an appeal be necessary.

Applicants respectfully request that this amendment be considered and entered.

II. The Rejections Under 35 U.S.C. § 112, Second Paragraph, Should Be Withdrawn

Claims 9, 18, 24 and 30 stand rejected as allegedly indefinite. Applicants respectfully traverse these rejections.

Claim 9 depends from cancelled Claim 8. Applicants propose to amend Claim 9 to depend from pending Claim 7. Applicants respectfully request that the amendment of claim 9 be entered, and that this rejection be withdrawn.

In Claim 18, the Examiner objects to the term "antibody half molecule." Applicants respectfully disagree, because one of ordinary skill in the art would have understood that the term "antibody half molecule" refers to a structure that contains one antibody heavy chain and one antibody light chain. *See* U.S. Patent No. 4,470,925 (copy attached) at column 1, lines 26-27. Applicants respectfully request that this rejection be reconsidered and withdrawn.

The Examiner objects to the term "unit dose" in claims 24 and 30. Applicants respectfully traverse this rejection. One of ordinary skill in the art would have understood that in a unit dose, medication is dispensed in a package that is ready to administer to a patient. Indeed, the term "unit dose" is recited in the claims of

hundreds of patents that issued prior to the December 29, 1999 international filing date of the application to which the present application claims priority, as shown in the attached MicroPatent search report cover page.

Applicants respectfully request that this rejection be reconsidered and withdrawn.

III. The Rejection Under 35 U.S.C. § 102 Should Be Withdrawn

Claims 7, 9 and 17-30 stand rejected as allegedly anticipated by Adema[1] The Examiner relies on Bost[2] and Bendayan[3], to allegedly show that antibody binding of distinct proteins was specific. Applicants respectfully traverse this rejection.

Applicants propose to amend Claim 7 to recite an antibody or fragment thereof which specifically binds to an isolated polypeptide consisting of the amino acid sequence of SEQ ID NO: 6, wherein when the antibody or fragment thereof is contacted with a sample suspected to contain the polypeptide of SEQ ID NO: 6 under conditions in which a stable antigen-antibody complex can form between the antibody or fragment thereof and the polypeptide in the sample, any antigen-antibody complex formation is detected, wherein detection of an antigen-antibody complex indicates the presence of the polypeptide of SEQ ID NO: 6 in the sample.

In Claim 7, as Applicants propose to amend it, the recited antibody or fragment thereof specifically binds the polypeptide of SEQ ID NO: 6, but does not specifically bind other antigens. That is because if an antigen-antibody complex formation is detected, it must be the polypeptide of SEQ ID NO: 6 that is specifically bound by the antibody or fragment thereof. Thus, binding of by the claimed antibody or fragment there of to the polypeptide disclosed in Adema is excluded.

Applicants respectfully request that the proposed amendment of claim 7 be entered, and that this rejection be reconsidered and withdrawn.

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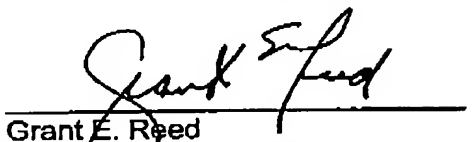
[1] Adema *et al.*, publication no. WO 98/24906.

[2] Bost, K.L. and Pascual, D.W., *Immunological Investigations 17(6&7)*: 577-586 (1988).

[3] Bendayan, M., *J. Histochemistry and Cytochemistry 43(9)*: 881-886 (1995).

It is believed that each of the Examiner's objections and rejections have been addressed herein.

Respectfully submitted,



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Search scope: US Granted; Claims
Years: 1971-2006
Text: "unit dose" **Issue/Publication Date:** <19991229

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1. US6008228A [ ] A61K 19991228 Hoffman-La Roche Inc.
Pharmaceutical compositions containing proteinase inhibitors

2. US6006916A [ ] A45D 19991228 Color Prelude, Inc.
Cosmetic sampler with applicator backing

3. US6004983A [ ] C07D 19991221 Novo Nordisk A/S
N-substituted azaheterocyclic compounds

4. US6004561A [ ] C07K 19991221 Baxter Aktiengesellschaft
High level expression of polypeptide that contains modified preS1 region of hepatitis B virus large antigen